# In the United States Court of Federal Claims

# OFFICE OF SPECIAL MASTERS No. 21-0101V UNPUBLISHED

SAMUEL BEYER,

Petitioner.

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: February 21, 2023

Special Processing Unit (SPU); Findings of Fact; Site of Vaccination Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Jeffrey S. Pop, Jeffrey S. Pop & Associates, Beverly Hills, CA, for Petitioner.

Martin Conway Galvin, U.S. Department of Justice, Washington, DC, for Respondent.

# FINDINGS OF FACT<sup>1</sup>

On January 5, 2021, Samuel Beyer filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*<sup>2</sup> (the "Vaccine Act"). Petitioner alleges that he suffered a right shoulder injury related to vaccine administration ("SIRVA"), as defined in the Vaccine Table, after receiving an influenza ("flu") vaccine on November 20, 2019. Petition at 1, ¶ 4. In the alternative, he maintains that his right shoulder injury was vaccine caused. *Id.* at 1.

<sup>&</sup>lt;sup>1</sup> Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

<sup>&</sup>lt;sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find the flu vaccine Petitioner received was most likely administered in his right deltoid, as alleged (although other fact issues remain to be resolved).

## I. Relevant Procedural History

Based upon the prior concern that SIRVA was to be removed from the Vaccine Injury Table,<sup>3</sup> Mr. Beyer filed his petition without medical records in January 2021. Petition at 1. A few weeks later he filed his signed declaration<sup>4</sup> and vaccine record. Exhibits 1-2, filed Jan. 20, 2021, ECF No. 6. Because the vaccine record did not indicate the site of vaccination (Exhibit 2), Petitioner was granted subpoena authority to obtain additional documentation such as his consent form. ECF No. 9. In May 2021, he filed the remainder of his medical records, a supplemental signed declaration, and amended petition – all containing the same assertions but supplemented by additional detailed information and medical records citations. Exhibits 3-17, ECF Nos. 10-11; Amended Petition, ECF No. 12.

A few months later, Petitioner filed the additional documentation obtained from the vaccine administrator. Exhibits 18-19, filed Aug. 31, 2021, ECF No. 15. Like the initial vaccine record (which indicated only that the flu vaccine was administered intramuscularly (Exhibit 2)), this documentation failed to show the site of vaccination. *Id.* 

Following the activation of the case to the "Special Processing Unit" (OSM's adjudicatory system for resolution of cases deemed likely to settle) (ECF No. 17), Petitioner was instructed to file medical records from a previous primary care provider ("PCP"), additional situs evidence, and a more detailed affidavit and evidence regarding the Vaccine Act's severity requirement. ECF No. 20. In response, Petitioner filed a better copy of his vaccine consent form, additional medical records, briefing on both factual issues, signed declarations from family and friends, and medical literature. Exhibits 20-38, Petitioner's Brief Regarding Situs and Severity Requirement ("Brief") ECF Nos. 21, 26-27, 29-30.

<sup>&</sup>lt;sup>3</sup> On July 20, 2020, the Secretary of Health and Human Services proposed the removal of SIRVA from the Vaccine Injury Table. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Proposed Rule, 85 Fed. Reg. 43794 (July 20, 2020). The proposed rule was finalized six months later. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Final Rule, 86 Fed. Reg. 6249 (Jan. 21, 2021). Approximately one month later, the effective date for the final rule was delayed. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Delay of Effective Date, 86 Fed. Reg. 10835 (Feb. 23, 2021) (delaying the effective date of the final rule until April 23, 2021). On April 22, 2021, the final rule removing SIRVA from the Vaccine Table was rescinded. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Withdrawal of Final Rule, 86 Fed. Reg. 21209 (Apr. 22, 2021).

<sup>&</sup>lt;sup>4</sup> Petitioner's declaration is signed under penalty of perjury as required by 28 U.S.C.A. § 1746. Exhibit 1.

Because the record as it currently stands contains sufficient evidence regarding the site of vaccination, I am addressing this issue prior to the HHS review. Before determining the length of Petitioner's sequela, however, I will allow Respondent to present argument on the issue, if desired.

#### II. Issue

At issue is whether Petitioner received the vaccination alleged as causal in his injured *right* deltoid, as alleged.

# III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at \*20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, \*4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to

document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

# IV. Finding of Fact

I make these findings after a complete review of the record, which includes all medical records, affidavits or signed declarations, and additional evidence filed. Specifically, I highlight the following:

 Petitioner (21 years old at the time of vaccination) experienced previous cervical and neck pain in 2017. Exhibit 9 at 9-10.

- In early 2019, his PCP noted diagnoses of asthma, anxiety, and depression. Exhibit 3 at 35. It also appears he had suffered a concussion previously (*id.*) and from a migraine in February 2019 (*id.* at 10).
- In May 2019, Petitioner was seen by his orthopedist for chronic left upper chest/shoulder pain which worsened "when reaching up or across [his] body." Exhibit 4 at 6. The onset of Petitioner's pain was identified as May 1, 2018. *Id.* at 8. The results of x-rays taken that day, were unremarkable, and Petitioner was instructed to apply ice and take over the counter pain medication. *Id.* at 9-10.
- On November 22, 2019, Petitioner received the flu vaccine alleged as causal at a Rite Aid Pharmacy. Exhibits 2, 19-20. The initial vaccine record indicates only that the vaccine was administered intramuscularly. Exhibit 2. Under site of administration, the record indicates "unknown." Exhibit 2. In the later provided consent form containing the usual notation: "Site RA or LA Circle One," neither option was circled. Exhibit 20 at 2 (most legible copy).
- Ten days post-vaccination (December 2, 2019), Petitioner visited his PCP complaining of "extreme soreness in his right deltoid" after receiving a flu shot on November 22<sup>nd</sup>. Exhibit 3 at 121. Stating that his pain worsened with abduction and the flexing of his forearm, he indicated he was taking 200mg of Ibuprofen for the pain. *Id.*
- On January 7, 2020, Petitioner returned to his PCP, now reporting a worsening of his right arm pain over the last ten days and inability to raise his arm to a parallel position (abduction) due to pain. Exhibit 3 at 139. Petitioner again related his pain to the flu vaccine he received on November 22<sup>nd</sup> at Rite Aid. *Id.* Concerned that Petitioner may have a rotator cuff or synovial issue in the glenohumeral joint, the PCP ordered an MRI. *Id.* This same history of right shoulder pain after receiving a flu vaccine two months earlier is found in the record from x-rays taken that day.
- The MRI performed on January 16, 2020, revealed evidence of fluid within the bursal and insertional fibers of the infraspinatus tendon near the humeral attachment and moderate thickening and fluid in the subdeltoid bursa. Exhibit 3 at 5. The likely cause was noted to be a low-grade insertional tendon tear, with reactive edema and bursitis. *Id.* at 6. Localized acute calcific tendinitis/bursitis was considered, but the MRI report showed no evidence of calcium on the MRI or x-rays. *Id.*

When seen by an orthopedist on January 30<sup>th</sup>, Petitioner reported that he "had a flu shot around the beginning of Dec. 2019, and his shoulder has hurt ever since." Exhibit 4 at 11. In this record, the onset of his right shoulder pain is described as "[t]he very next day." *Id.* at 12. The orthopedist diagnosed Petitioner with bursitis and administered a Depo-Medrol injection. *Id.* at 13.

The above medical entries show that, when seeking treatment for his right shoulder pain, Petitioner consistently attributed his pain to a vaccination he reported receiving in his right arm. While originating from Petitioner, these statements are memorialized in contemporaneous records, and should therefore be afforded greater weight than any subsequent assertion or witness statement. The Federal Circuit has stated that "[m]edical records, in general, warrant consideration as trustworthy evidence . . . [as they] contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions." *Cucuras*, 993 F.2d at 1528 (emphasis added). Thus, and even though the record in question simply memorializes what the petitioner said at the time, its contemporaneous nature makes it somewhat more trustworthy than after-the-fact witness statements prepared in connection with this matter.

The vaccine record clearly establishes that Petitioner received a flu vaccine on November 22, 2019, but is silent as to the site of administration. Not long thereafter, however, when seeking medical care for his right shoulder pain, Petitioner consistently attributed the source of his pain to the flu vaccine. There is a dearth of evidence that the vaccine was administered in any other location. I thus determine, based on the record as a whole, that preponderant evidence establishes that the flu vaccine to which Petitioner attributes his SIRVA was most likely administered in his *right* deltoid on November 22, 2019.

## V. Sequela of Alleged Injury

To satisfy the Vaccine Act's severity, Petitioner must establish that he suffered the residual effects of his injury for more than six months – beyond May 22, 2020, or that he required inpatient hospitalization and surgical intervention. Section 11(c)(1)(D). Citing the information contained in his medical records – including the statements of his treating physicians, signed statements from himself and others, and submitted medical literature, Petitioner maintains he has provided sufficient evidence of both six-month sequela and the required surgical intervention. Brief at 14-22.

Petitioner sets forth persuasive arguments to support his assertion that the right shoulder pain he suffered in the second half of 2020 – following a seven-month gap in

treatment he attributes to temporary relief obtained from the first steroid injection he received - was linked to his earlier vaccine-related pain. See, e.g. Brief at 16 (citing Exhibit 4 at 26 containing the orthopedist's opinion that earlier and later MRIs showed findings in the same area). And the medical records show that both Petitioner and his treating physicians viewed this later 2020 pain as a continuation of his earlier condition, despite the seven-month gap in treatment. See Exhibit 3 at 185-99 (September PCP visit); Exhibit 4 at 23-26 (November orthopedic visit). Moreover, it is common for petitioners to experience several months of temporary pain relief after receiving a steroid injection.

However, Petitioner also appears to have suffered from some conditions not necessarily related to the vaccine he received – such as a shoulder labral tear. See, e.g. Exhibit 24 at 6-8 (results of July 2021 MRI); Exhibit 27 at 78-80 (December 2021 surgery). And the record clearly indicates he suffered *left* shoulder, neck, and cervical pain as recent as early 2019. Exhibit 4 at 6-10. At a minimum, these other potential co-morbidities will affect the amount of any compensation awarded in this case – and arguably could be a complete bar to compensation, depending on their resolution.

# VI. Scheduling Order

Because the HHS review has not yet been completed in this case, but is likely occurring now, I will allow Respondent the opportunity to provide his tentative position and briefing regarding the severity issue - if he believes this requirement has not been met. However, I encourage the parties to attempt an informal resolution of this case. Therefore, Petitioner should finalize a *reasonable* demand - which he may convey, along with any supporting documentation, to Respondent at any time.

Respondent shall file a status report providing his tentative position regarding the merits of Petitioner's case by no later than <u>Wednesday</u>, <u>March 22</u>, <u>2023</u>. In the status report, he should state whether he believes Petitioner has satisfied the Vaccine Act's severity requirement.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master